K103212

510(K) Summary

for

Whirlwind RoughRider® Manual Wheelchair

JAN - 3 2010

This summary of 510(k) safety and effectiveness information is being supplied in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92

The assigned 510(k) number is: .... Unassigned

Date: ..... October 19, 2010

Submitted by: ..... Whirlwind Wheelchair International
Agency Tracking ID: 50018822
1600 Holloway Ave., SCI 251
San Francisco, CA 94132

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Contact Person: ..... Mr. Marc Krizack
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Proprietary/Trade Name: ..... RoughRider® wheelchair
Common Name: ..... Manual wheelchair
Classification Name: ..... Wheelchair, mechanical per 21 CFR 890.3850
FDA Product Code: ..... IOR
Proposed FDA Classification: ..... Class I
Panel Code: ..... Physical Medicine

Legally Marketed Predicate Device: Invacare Tracer Ex2
510K#: K935398
FDA Class: Class 1
Granted Clearance: March 1, 1994

Device Description:
The Whirlwind RoughRider® is a user propelled, manually operated folding wheelchair. The Whirlwind RoughRider has not previously been submitted to the FDA for clearance. The Whirlwind RoughRider utilizes carbon steel tubing (STKM 11 AC) that is bent, fastened and/or welded to create a frame. An X-Brace connects the left and right mono frame (single piece side frame design) side frames of the wheelchair together and serves as the mechanism that allows the frame to fold. A set of adjustable axle sockets are attached to each side frame which provide the wheelchair with ability to move the rear wheel position forward and backward to give the user an adjustment as to the center of gravity of the wheelchair. Front casters (hubs and tires) are connected to a fork that is fastened to the front frame of the chair at the caster housing. The front casters of the RoughRider are positioned approximately five inches further forward than most wheelchair designs, which gives the user of the RoughRider a very stable ride in terms of forward stability. The RoughRider is intended for use on smooth indoors surfaces and outdoor surfaces which require additional forward stability such as pocked dirt and uneven pavement. The nylon upholstery back and seat meets EN 1021-1 and EN 1021-2: Flammability Testing with Match and Cigarette.

Intended Use: To provide mobility to persons restricted to a seated position. The wheelchair is indicated for a weight capacity of up to 220 lbs.

Substantial Equivalence: A product that is substantially equivalent to the RoughRider is the Invacare Tracer Ex2 , K935398, March 1, 1994. The RoughRider is comparable to the Invacare Tracer Ex2 wheelchair in its intended use, construction and functionality.

Both wheelchairs feature X-Brace style folding frames, non-removable armrests, non-removable footrests, and are manually operated and meant to provide mobility to persons restricted to a sitting position. Both wheelchairs feature a fabric seat sling over an X-Brace style of folding mechanism. Both wheelchairs' footrests have the ability to be flipped up to allow open entrance for the riders' entry and exit from the wheelchair. Both wheelchairs' footrests are fixed laterally and do not swing away. Both wheelchairs frames are manufactured from carbon steel. Both wheelchairs are similar in weight and folding dimensions. Both the Whirlwind RoughRider and the Invacare Tracer Ex2 use solid rubber non-pneumatic front caster tires. Both wheelchairs are propelled using a manual push rim.

The main differences between the two devices are as follows:

- The Whirlwind RoughRider differs in the area of rear wheel position options in that the RoughRider offers 5 horizontal axle positions. The Invacare Tracer Ex2 wheelchair has 2 vertical axle positions.
- The front casters on the Whirlwind RoughRider are positioned approximately 5 inches further forward on the wheelchair making a longer wheelbase for added stability as compared to the front casters on the Invacare Tracer Ex2.
- The Whirlwind RoughRider wheelchair has a weight capacity of up to 220 lbs. and the Invacare Tracer Ex2 has a weight capacity of up to 250 lbs.

Performance Standards: Although no performance standards or special controls have

been developed under Section 514 of the FDC Act for manual wheelchairs, the Whirlwind RoughRider has been tested in accordance with the standards referenced in this submission.

Summary: The RoughRider and the predicate device have the same intended use, construction and functionality. The major differences existing are the additional horizontal axle positions, longer wheelbase for additional stability, and the lower weight capacity. The RoughRider is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Whirlwind Wheelchair International
% Mr. Marc Krizack
Executive Director
1600 Holloway Avenue, SCI 251
San Francisco, California 94132

Re: K103212
Trade/Device Name: The RoughRider®
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: October 22, 2010
Received: November 1, 2010

JAN - 3 2010

Dear Mr. Krizack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K103212

510(k) Number: Unassigned

JAN - 3 2010

Device Name: The RoughRider®

Indications for Use: The RoughRider is indicated to provide mobility to persons restricted to a seated position. The wheelchair is indicated for a weight capacity of up to 220 lbs.

Prescription Use _____ AND/OR Over-The-Counter Use _X_
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103212